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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,344	04/04/2008	Lawrence Solomon	SLP-036	2815

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EXAMINER	
LOVE, TREVOR M	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,344	SOLOMON ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8 and 10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 02/18/2010

Claims 1-7 and 9 are cancelled.

Claims 8 and 10-13 are pending

Claims 8, 10, and 11 are currently amended.

Claims 8 and 10-13 are currently under consideration.

It is noted that claims 8 and 10 are improperly identified as being "previously presented".

Specification

Applicant's amendment to the specification filed 02/18/2010 is acknowledged.

Withdrawn Rejections

The objection to the specification for failing to contain reference to the priority documents has been withdrawn in view of Applicant's amendment to the specification filed 02/18/2010.

The rejection of claims 9-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicant's cancellation of claim 9, and Applicant's amendments to claims 8, 10, and 11.

The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Lieberman (Pharmaceutical Dosage Forms - tablets, 1990) in view of Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980) and Geller (U.S. Patent number

3,927,194, Patent issued Dec. 16, 1975) is withdrawn in view of Applicant's cancellation of said claim.

The provisional rejection of claim 9 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 53 of copending Application No. 10/598,355 is withdrawn in view of Applicant's cancellation of said claim.

New Grounds of Rejection and/or Objection

Claim Rejections - 35 USC § 112

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 10 recites a method wherein there is no active method step. Furthermore, claim 10 was improperly amended wherein the entirety of the previously presented text is not present. For the sake of compact prosecution, the claim is being interpreted as possessing the previously recited method steps, wherein the underlined portions of the current claims are being included to further define the invention. Specifically, for the sake of compact prosecution, the claim is being interpreted as reading:

10. (currently amended) : A method of breaking a pharmaceutical tablet as defined in claim 8 which comprises breaking said tablet through a score where the distance that said score extends from the top surface of the first segment to said interface is no less than 70% of the distance from the top surface of the first segment to said interface.

Appropriate correction is required. Should Applicant believe that the claim is written correctly in the claim set filed 02/18/2010, the claim is rejected for being in improper form for lacking an active step.

Rejections Maintained and Made Again - in view of Applicant's amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieberman (1990, Pharmaceutical Dosage Forms - tablets) in view of Ullman et al (U.S. Patent number 4,215,104, Patent issued Jul. 29, 1980) and Geller (U.S. Patent number 3,927,194, Patent issued Dec. 16, 1975). This rejection is maintained and made again.

Lieberman teaches a pharmaceutical dosage form with layers. Lieberman teaches that it is known to have a tablet wherein the center layer is free of active. Lieberman teaches said middle inert layer for when the two outer actives are incompatible (see first paragraph under “IV. Layer Tablets”). Lieberman further teaches that it is known to place scores on tablets to allow for manual breakage, however, Lieberman acknowledges that traditional scores result in significant variation in drug dose (see point number 4 under "Properties of Tablets"). Lieberman further teaches that the purpose of a score is "to permit breaking the tablet into equal parts for the administration of half a tablet" (see point number 4 under "Properties of Tablets").

Lieberman fails to directly teach that there are only two layers to the tablet, or the particular location of the score, or the instant active ingredient.

Ullman teaches a multi-fractionable unitary tablet structure. The tablet has a score which transverses the entire tablet.

Geller teaches deeply scored tablets (up to 66% of the entire tablet) wherein the active ingredient is isosorbide dinitrate (see column 2, lines 28-33 and claim 6). Geller

further identifies the art recognized deficiency in scored tablets i.e. "scores do not always assure precise division of the tablet" (see column 1, lines 40-41).

It would have been obvious to one or ordinary skill in the art at the time the invention was made to utilize the tablet structure of Ullman with the layers described in Lieberman. One would have been motivated to do so since Ullman provides a clear teaching of a superior scored tablet which allows for the tablet to be broken into two separate dosages. There would be a reasonable expectation of success since both Lieberman and Ullman are teaching scored tablets.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the top and bottom portion of the tablet design of Ullman for the incompatible active ingredients of Lieberman. One would have been motivated to do so since Lieberman teaches that variable dosing is a well known problem in the art associated with breaking dosage forms. Furthermore, utilizing the top and bottom segment of Ullman allows for breakage to only occur in the inert barrier layer. There would be a reasonable expectation of success since Lieberman teaches that trilayered tablets with an inert barrier layer can be scored.

It further would have been obvious to one of ordinary skill in the art at the time the invention was made, given the scored trilayered tablet of Lieberman and Ullman which comprises two incompatible drugs separated by a barrier layer, to remove one of the drug layers of the composition of Lieberman and Ullman, should one desire to only deliver one of the actives, such as is taught in Geller, namely a scored tablet with only one active. One would have been motivated to retain the inert barrier layer since said

barrier layer has allowed for the overcoming of the well known problem in the art of variable dosages. There would be a reasonable expectation of success since the removal of one of the actives would not affect the dosage of Lieberman and Ullman. It is further noted that removal of one of the actives is clearly obvious if one only desires to deliver one active, see MPEP 2144.04, which states: “Omission of an element and its function is obvious if the function of the element is not desired (see *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize drugs directed toward the treatment of cardiovascular conditions in the tablet of Lieberman in view of Ullman. One would have been motivated to do so since Geller teaches that it is useful to be able to provide divided doses of isosorbide dinitrate. There would be a reasonable expectation of success in the use of isosorbide dinitrate since as is seen by Geller, isosorbide dinitrate is known to be advantageously administered by tablets which can be broken into smaller dosing units.

With regard to the distance of said score, it is noted that the instant claims are directed to the score being "at least” or “no less than” 70% of the distance from the top of the first layer to the interface (namely, the first layer), wherein it is noted that the teachings of Geller are that the score is 66% of the entire tablet. Therefore, the score of Geller which is 66% through the entirety of the tablet reads on the limitation of 70% or more through only the first layer.

Response to Arguments

Applicant argues in the remarks filed 02/18/2010 that the teachings of multilayered tablets and scores in Lieberman are unconnected and are found in different portions of the reference. Applicant's arguments are not found persuasive since, as is clearly seen by page 274 of Lieberman, the section discussing layered tablets directly states that "markings may be impressed in the surfaces of the multilayered tablet", wherein the best place to look for what said markings can be would be within the same reference. Hence, when Lieberman teaches on page 132 that "[a]nother marking that may appear on the tablet is a score", it is clear that Lieberman is teaching that multilayered tablets can be scored. Applicant further argues that the reliance upon Ullman is improper since "[i]t is not seen where Ullman teaches a top and bottom segment where breakage may occur. The tablet of Ullman is a homogeneous tablet and it is not a two layered tablet" (see remarks, page 7). Applicant's argument is not found persuasive since the tablet structure of Ullman is being relied upon as modification of the multilayered tablet of Lieberman. Motivation exists since Lieberman teaches that the multilayered tablet can be scored, wherein Lieberman fails to provide further guidance as to the best locations and depths for said scored. The score locations of Ullman provide for increased flexibility in dosing and increased ease of use. Applicant further argues that “[t]he deficiency in the rejection is that the cited prior art does not even describe a two layered tablet as defined in amended claim 8 and thus there is no prior art two layered tablet with a score that could be broken through any layer" (see remarks, page 8). Applicant’s argument is not found persuasive. Specifically, it is noted that it would have been obvious to one of ordinary skill in the art

at the time the invention was made, that upon identification of the benefits of the trilayered scored tablet, one would clearly desire the same feature (reduced breakage through active layer) to avoid dosage variation when delivering only one active. Furthermore, *Ex parte Wu* (10 USPQ 2031 (Bd. Pat. App. & Inter. 1989)), clearly sets forth precedent for the removal of a component that has a specific function that is no longer desired (such as a second active). Furthermore, it is not only obvious, but necessarily logical that when an inert layer functions to decrease the amount of active broken through in a three layered tablet, that said inert layer would also provide said same advantage in a bi-layered tablet. Finally, Applicant argues that the instant tablet differs from that of Geller since Geller teaches ""separation into subdivisions containing ***substantially*** equal amounts of pharmaceutically active ingredients". Nothing in Geller disclosed a concept of providing "equal" amounts of pharmaceutically active ingredients" (see remarks, page 10). It is noted that Applicant is not claiming providing "equal amounts of pharmaceutically active agents", wherein it is further noted that the instant claims simply state that the score must be "at least" or "no less than" 70% of the first layer, therefore, at least some active agent will be broken through, which will cause at least some variation in the amount of active. Therefore, in view of the above, Applicant's arguments, while being fully considered, are not found persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8 and 10-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 53 of copending Application No. 10/598,355.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and '355 are directed to a bilayered tablet wherein the first layer comprises active and the second layer is substantially free of drugs. Both compositions are score, and are designed to be broken and administered.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant states that a terminal disclaimer will be filed upon indication of allowable subject matter. Applicant's argument has been considered, however, since

the claims are not in condition for allowance, and a terminal disclaimer has not been filed, the rejection is maintained.

Conclusion

No claims allowed. All claims rejected. No claims objected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643